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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kazutoshi Fujii

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EXAMINER

SINGH, ANOOP KUMAR

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,224	Applicant(s) FUJII ET AL.	
	Examiner ANOOP SINGH	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-27, 50, drawn to a sucrose phosphorylase having improved thermostability, which is obtained by modifying a natural sucrose phosphorylase selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 16, SEQ ID NO: 18 , SEQ ID NO: 20 and variant thereof.

Group II, claims 28-39, 51, drawn to a method for producing sucrose phosphorylase having improved thermostability, comprising: modifying a first nucleic acid molecule comprising a base sequence encoding a first sucrose phosphorylase to obtain a second nucleic acid molecule comprising a modified base sequence; preparing an expression vector containing the second nucleic acid molecule ;introducing the expression vector into a cell to express sucrose phosphorylase having improved thermostability; and recovering the expressed sucrose phosphorylase having improved thermostability.

Group III, claims 39-42, drawn to a nucleic acid molecule comprising a base sequence encoding the sucrose phosphorylase encoding amino acid selected from group consisting of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 16, SEQ ID NO: 18 and SEQ ID NO: 20 or variants thereof, vector and cell comprising said nucleic acid.

Group IV, claims 43-44, 52, drawn to a method of synthesizing glucose-1-phosphate, comprising

Art Unit: 1632

reacting a reaction solution containing the sucrose phosphorylase having improved thermostability according to claim 1, sucrose and inorganic phosphoric acid to produce glucose-1-phosphate or glucose .

Group V, claims 45-49, 53, drawn to a method of synthesizing a glucose polymer, comprising reacting a reaction solution containing the sucrose phosphorylase having improved thermostability according to claim 1; a second phosphorylase using .alpha.-glucose-1-phosphate as a substrate; sucrose; a primer; and inorganic phosphoric acid or glucose-1-phosphate to produce a glucose polymer.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking group I-V is a sucrose phosphorylase that is a variant of natural sucrose phosphorylase selected from the group consisting of variants of SEQ ID NO: 2. Tettelin et al (Science 293, 498-506, 2001 and GenBank accession no D95221) teach a mutant sucrose phosphorylase that has at least 40% sequence homology with SEQ IN NO: 2 meeting the limitation of the claim. Since the structure of sucrose phosphorylase is structurally similar to one claimed in the instant application hence the mutant SP disclosed by Tettelin et al must necessarily inherently have same improved thermostability as disclosed by the claimed SP. Therefore, the instant technical feature does not contribute over prior art.

In addition, the inventions are distinct, each from other because of the following reasons: In the instant case, the amino acid (group I) is distinct from using nucleic acid encoding protein (group II), vector or cell comprising nucleic acid (group III), producing glucose -1phosphate (group IV) or glucose polymer (group V) because they require distinct composition and/or method steps to practice and therefore, searching for distinct special technical feature will not be coextensive and will require separate and independent searches in the patent and non-patent literature. In view of foregoing it is clear that each invention is directed to distinct goal, which comprises the use amino acid, nucleic acid encoding protein or cell comprising nucleic acid in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-V do not relate to a single general

Art Unit: 1632

inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: sucrose phosphorylase having improved thermostability has an amino acid residue which is different from that of the natural sucrose phosphorylase in at least one position selected from the group consisting of:

(i) a position corresponding to position 14, a position corresponding to position 29 and a position corresponding to position 44 in motif sequence 1:

AVGGVHLLPFFPSTGDRGFAPIDYHEVDSAFGDWDDVKRLGEKYYL

MFDFMINHI S; a position corresponding to position 7, a position corresponding to position 19, a position corresponding to position 23 and a position corresponding to position 34 in motif sequence 2: RPTQEDVDLIYKRKDRAPKQEIQFADGSVEHLWNTFGEEQID; and a position corresponding to position 19 in motif sequence 3: ILPEIHEHYTIQFKIADHDYYVYDFA LPMVTLYSLYSG.

(ii) natural sucrose phosphorylase in at least one position selected from the group consisting of: a position corresponding to threonine at position 47 (T47); a position corresponding to serine at position 62 (S62); a position corresponding to tyrosine at position 77 (Y77); a position corresponding to valine at position 128 (V128); a position corresponding to lysine at position 140 (K140); a position corresponding to glutamine at position 144 (Q144); a position corresponding to asparagine at position 155 (N155); and a position corresponding to aspartic acid at position 249 (D249); in the amino acid sequence of SEQ ID NO: 2;

Applicant is required, in reply to this action, to elect a single or specific combination of modification to an amino acid sequence to which the claims shall be restricted if no generic claim is finally held to be allowable.

Further upon election of a single or specific combination of sequence applicant must further elect one single corresponding amino acid sequence that is modified selected from the

Art Unit: 1632

group consisting of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 16, SEQ ID NO: 18 and SEQ ID NO: 20.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 1-5, 28-32, 40, 43, 45, 50 and 51

The claims are deemed to correspond to the species listed above in the following manner: claims 1, 28-32, 40, 43, 45, 50 and 51, and claims dependent therefrom correspond to all the species listed above.

The following claims are generic: 1, 28-32, 40, 43, 45, 50 and 51.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: since each of these protein types do not share a common structure feature with respect to their sequence structure. Thus, requirement of unity of invention is not fulfilled.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: wherein the natural sucrose phosphorylase is derived from a bacterium selected from the group consisting of *Streptococcus mutans*, *Streptococcus pneumoniae*, *Streptococcus sorbinus*, *Streptococcus mitis*, *Leuconostoc mesenteroides*, *Oenococcus oeni*, *Lactobacillus acidophilus* and *Listeria monocytogenes*;

Applicant is required, in reply to this action, to elect a single species of bacterium to which the claims shall be restricted if no generic claim is finally held to be allowable.

Art Unit: 1632

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claims are generic: 1, 6, 28, 33, 50 and 51.

The claims are deemed to correspond to the species listed above in the following manner: claims 1, 6, 28, 33, 50 and 51, and claims dependent therefrom correspond to all the species listed above.

The following claims are generic: 1, 6, 28, 33, 50 and 51.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: since each of these bacterium types do not share a common structure feature with respect to their structure and function. Thus, requirement of unity of invention is not fulfilled.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is

Art Unit: 1632

provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

Art Unit: 1632

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anoop Singh/
Examiner, Art Unit 1632